AmeriWater

1303 STANLEY AVENUE
DAYTON, OH 45404 USA
TEL 937-461-8833, 800-535-5585
FAX 937-461-1988
www.AMERIWATER.com

February 27, 2014

510(K) SUMMARY

510(K) Number:	K133783
Submitter:	AmeriWater
Contact:	Brian R. Bowman, Quality & Regulatory Administrator 1303 Stanley Avenue, Dayton, OH 45404 Phone: (937)461-8833 Fax: (937)461-1988 brianbowman@ameriwater.com
Proprietary Name:	AmeriWater Centurion 1500+ Reverse Osmosis System
Common Name:	Reverse Osmosis System
Classification Name:	Water purification system for hemodialysis
Classification:	Class II Medical Device under §876.5665 Panel: Gastroenterology Product Code: FIP
Equivalent Devices:	K131904, AmeriWater MediQA Reverse Osmosis System K111740, AmeriWater MRO Portable Reverse Osmosis System MROS

Device Description: The AmeriWater Centurion 1500+ Reverse Osmosis System is a water treatment system intended for use in hemodialysis applications. The system is designed to remove organic and inorganic substances and contaminants from potable water. The purified (or treated) water will then be used to prepare and dilute dialysate concentrate to form dialysate. The AmeriWater Centurion 1500+ Reverse Osmosis System is intended to be used in hospitals, clinics, dialysis centers, and for home care use. There is no direct contact between the patient and any part of the device nor is the device invasive. Materials that contact the product water include: Nylon, Polypropylene, Stainless Steel, EPDM, and Thin Film Composite Membrane (Polyamide). The Centurion 1500+ Reverse Osmosis System purifies water by applying pressure (greater than the osmotic pressure difference) to the feed water to reverse the water flow through a semi-permeable membrane so that the water moves from a more concentrated solution to a less concentrated solution resulting in purified permeate flow. The feed water enters the Centurion through an inlet solenoid valve filling the feed water tank. A high pressure pump forces water from the feed tank through the RO membrane where it is split into permeate which has passed through the membrane and the concentrate which passes over the membrane and carries the contaminants to drain. The AmeriWater Centurion 1500+ Reverse Osmosis System produces water that meets current AAMI and Federal (U.S.) standards for water used in hemodialysis applications.

The AmeriWater Centurion 1500+ Reverse Osmosis System also includes a built in heat sanitization feature. Heat sanitization can be activated manually using the HEAT SANITIZATION function from the controller's main menu. The frequency of thermal sanitization will depend upon usage and application demands. Monitoring of the system for bacterial content should be conducted at regular intervals to determine the optimum frequency for thermal sanitization.

Indications for Use: The AmeriWater Centurion 1500+ Reverse Osmosis Systems are water treatment systems intended for use in hemodialysis applications. They are designed to pre-treat and purify potable water for use in making dialysate for hemodialysis and to meet current AAMI and Federal (U.S.) standards. The device is intended to be a component in a complete water purification system, and is not a complete water treatment system. It must be preceded by pre-treatment devices, and may need to be followed by post-

treatment devices as well to meet current AAMI and Federal (U.S.) standards. The Centurion 1500+ Reverse Osmosis System is intended for use in a hospital, clinic, dialysis center, or for home care for single patient use. The device includes an integrated heat sanitization process.

Statement of Substantial Equivalence: The AmeriWater Centurion is substantially equivalent to the AmeriWater MRO Portable Reverse Osmosis System (MROS) cleared for market under K111740, and the AmeriWater MediQA Reverse Osmosis System cleared for market under K131904. The following table compares and contrasts the predicate devices and the new device. This table along with the documentation included in this submission demonstrates that there are no new issues of safety or effectiveness associated with this design change, and that the new device is substantially equivalent to the predicate device.

	Predicate Device AmeriWater MEDIQA (K131904)	**Predicate Device** AmeriWater MROS (K111740)	**AmeriWater Centurion 1500+**
Indications for use	The AmeriWater MediQA Reverse Osmosis System is one component of a water treatment system designed to pre-treat and purify potable water using reverse osmosis for making dialysate for hemodialysis applications. The device is intended to be a component in a complete water purification system, and is not a complete water treatment system. It must be preceded by pre-treatment devices, and may need to be followed by post-treatment devices as well to meet current AAMI and Federal (U.S.) standards. The AmeriWater MediQA is intended for use in water rooms in a hospital, clinic, or dialysis center. The device includes an integrated heat sanitization process.	The AmeriWater MRO Portable Reverse Osmosis Systems are water treatment systems intended for use in hemodialysis applications. They are designed to pre-treat and purify potable water for use in making dialysate for hemodialysis and to meet current AAMI and Federal (U.S.) standards. The AmeriWater Portable MROS model is intended for use in a hospital, clinic, dialysis center, or for home care for single patient use. The AmeriWater Portable MRO1 model is for treatment of up to two patients in a hospital, clinic, or dialysis centers.	The AmeriWater Centurion 1500+ Reverse Osmosis Systems are water treatment systems intended for use in hemodialysis applications. They are designed to pre-treat and purify potable water for use in making dialysate for hemodialysis and to meet current AAMI and Federal (U.S.) standards. The device is intended to be a component in a complete water purification system, and is not a complete water treatment system. It must be preceded by pre-treatment devices, and may need to be followed by post-treatment devices as well to meet current AAMI and Federal (U.S.) standards. The Centurion 1500+ Reverse Osmosis System is intended for use in a hospital, clinic, dialysis center, or for home care for single patient use. The device includes an integrated heat sanitization process.
For Use In:	Hospitals, clinics, or dialysis centers	Hospitals, clinics, dialysis centers, home care	Hospitals, clinics, dialysis centers, home care
Power Requirements	208/230V; 60 Hz; 3-phase	115V 60 Hz 20 Amp	115V 60 Hz 20 Amp
Purification process	Reverse Osmosis	Reverse Osmosis	Reverse Osmosis
RO Membrane	Polyamide, thin film composite, spiral wound	Polyamide, thin film composite, spiral wound	Polyamide, thin film composite, spiral wound
Rejection rates	Total dissolved salts > 96%	Total dissolved salts > 94%	Total dissolved salts > 98%
Permeate Flow Rates	19 to 48 l/min at 10°C	1.8 l/min at 10°C	1.5 l/min at 10°C
Drain Requirements	Max 96 l/min	Max 3.6 l/min	Max 3.0 l/min
RO Disinfection	Chemical or Heat	Chemical	Chemical or Heat
Water Contacting Materials	Polyamide, Polypropylene, CPVC, Nitrile, EPDM, Stainless steel, Polyacetal, PTFE, Viton(FKM), Fiberglass, PA66 (Nylon), PET Noryl	ABS, Acrylic, Carbon, Nylon, PVC, Polyester, Polyethylene, Polypropylene, Stainless Steel, Tygon, Buna N	Nylon, Polypropylene, Stainless Steel, EPDM, and TFC Membrane (Polyamide)

Summary of Performance Testing: Non-clinical testing was conducted to verify and validate the performance of the reverse osmosis function and the efficacy of the heat sanitization in the reduction of bacteria. Results of performance testing indicate that the device produces water that meets current AAMI and Federal (U.S.) standards. Microbiological testing results show evidence that the heat sanitization function is effective in the reduction of bacteria. Clinical studies show evidence that the device, when used in accordance with the instructions for use, will produce water that meets current AAMI and Federal (U.S.) standards for hemodialysis. Test results from biocompatibility testing, software validation, and electrical safety testing (in accordance with IEC 60601-1) indicate that the device is safe and effective for its intended purpose.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 16, 2014

AmeriWater, Inc.
Brian R. Bowman
Quality and Regulatory Administrator
1303 Stanley Avenue
Dayton, OH 45404

Re: K133783
Trade/Device Name: AmeriWater Centurion 1500 + Reverse Osmosis System
Regulation Number: 21 CFR§ 876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: II
Product Code: FIP
Dated: March 12, 2014
Received: March 20, 2014

Dear Brian R. Bowman,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): **K133783**

Device Name: AmeriWater Centurion 1500+ Reverse Osmosis System

Indications For Use:

The AmeriWater Centurion 1500+ Reverse Osmosis Systems are water treatment systems intended for use in hemodialysis applications. They are designed to pre-treat and purify potable water for use in making dialysate for hemodialysis and to meet current AAMI and Federal (U.S.) standards. The device is intended to be a component in a complete water purification system, and is not a complete water treatment system. It must be preceded by pre-treatment devices, and may need to be followed by post-treatment devices as well to meet current AAMI and Federal (U.S.) standards. The Centurion 1500+ Reverse Osmosis System is intended for use in a hospital, clinic, dialysis center, or for home care for single patient use. The device includes an integrated heat sanitization process.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S
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